UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF MISSISSIPPI
SOUTHERN DIVISION

BIG TIME VAPES, INC., *et al.*,

Plaintiffs,

v.

U.S. FOOD AND DRUG ADMINISTRATION, *et al.*,

Defendants.

Civil Case No. 1:19-cv-531-LG-JCG

DEFENDANTS' REPLY MEMORANDUM IN SUPPORT OF MOTION TO DISMISS

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The Supreme Court "has over and over upheld even very broad delegations." *Gundy v. United States*, 139 S. Ct. 2116, 2129 (2019) (plurality opinion). Despite Plaintiffs' efforts to get out from under this mountain of adverse precedent, there is nothing sufficiently novel or unprecedented about the Tobacco Control Act that would justify a departure from that robust line of authority, unbroken since 1935. In fact, the statutory structure challenged here is virtually identical to one that the Fifth Circuit has already upheld in the face of a nondelegation challenge, making this case particularly easy. *See United States v. Womack*, 654 F.2d 1034 (5th Cir. 1981). The Tobacco Control Act is constitutional, and Plaintiffs' complaint should be dismissed, without the need for any discovery—let alone discovery about the irrelevant topics identified by Plaintiffs in their opposition brief.

I. THE TOBACCO CONTROL ACT DELEGATES NON-LEGISLATIVE POWER TO THE EXECUTIVE CONSISTENT WITH BINDING PRECEDENT.

Congress may delegate to the Executive so long as it "lay[s] down by legislative act an intelligible principle to which the person or body authorized to [act] is directed to conform." *J.W. Hampton, Jr., & Co. v. United States*, 276 U.S. 394, 409 (1928). Under that standard, a delegation is "constitutionally sufficient if Congress clearly delineates" (1) "the general policy" to be pursued, (2) "the public agency which is to apply it," and (3) "the boundaries of th[e] delegated authority." *American Power & Light Co. v. SEC*, 329 U.S. 90, 105 (1946). Plaintiffs appear not to dispute that this standard governs here. As explained in Defendants' combined memorandum in opposition to Plaintiffs' motion for a preliminary injunction and in support of Defendants' motion to dismiss ("Defs.' Combined Mem."), ECF No. 25, the deeming authority in the Tobacco Control Act, 21 U.S.C. § 387a(b), easily satisfies this lenient standard—particularly when the statute is interpreted as a whole, with an eye to Congress's purpose. Plaintiffs' arguments to the contrary fail to refute that showing, and their complaint should therefore be dismissed for failure to state a claim.

A. Congress identified the agency to which authority is delegated.

Plaintiffs do not dispute that Congress appropriately identified "the public agency which is to apply" the delegated authority. *American Power & Light*, 329 U.S. at 105.

B. Congress identified the limits of the delegated authority.

Congress also "clearly delineate[d] . . . the boundaries of th[e] delegated authority." *Id.* As Defendants have explained, Congress itself "made virtually every legislative determination" in the Tobacco Control Act, "which has the effect of constricting" the agency's remaining "discretion to a narrow and defined category." *United States v. Whaley*, 577 F.3d 254, 264 (5th Cir. 2009) (quoting in a parenthetical *United States v. Ambert*, 561 F.3d 1202, 1214 (11th Cir. 2009)). In particular, Congress accomplished its goals in this statute by first defining the term "tobacco product" with precision: as "any product made or derived from tobacco that is intended for human consumption, including any component, part, or accessory of a tobacco product (except for raw materials other than tobacco used in manufacturing a component, part, or accessory of a tobacco product)." 21 U.S.C. § 321(rr)(1); *see also id.* § 321(rr)(2) (placing further limitations on the definition of "tobacco product"); *id.* § 387a(c)(2)(A) (similar). *Congress* then imposed a series of detailed obligations on manufacturers and retailers of "tobacco products." *See* Defs.' Combined Mem. at 26-27 (citing, for example, obligations imposed by 21 U.S.C. §§ 387d(a)(1)-(2), 387c, 387f(d)(1)-(2), 387k, 387e(b), 387e(i), 387j(a)(1)-(2), 387j(b)-(c), 387j(a)(2)(A)(i), 387e(j)(1), 387j(a)(2)(A)(ii), 387e(j)(3), and 387a-1(a)).

Having addressed those statutory obligations in detail, Congress then (1) applied them to a defined subset of listed "tobacco products" (*i.e.*, "cigarettes, cigarette tobacco, roll-your-own tobacco, and smokeless tobacco"), and (2) delegated to the Executive Branch the authority to "by regulation deem[]" "any other tobacco products"—*i.e.*, other "tobacco products" not listed in the preceding clause, but that still meet the definition in 21 U.S.C. § 321(rr)—"to be subject to this subchapter." *See*

id. § 387a(b). FDA thus "is left only with the discretion to determine" whether the requirements "articulated by the legislature apply" to "a narrow and defined category," *Ambert*, 561 F.3d at 1214, of "tobacco products" defined in 21 U.S.C. § 321(rr).

This is not the first nondelegation challenge to a statute structured in this way. In *United States v. Womack*, the Fifth Circuit rejected a nondelegation challenge to a statute that, just like the Tobacco Control Act, imposed fixed statutory requirements with respect to a congressionally defined category ("explosives"), but delegated to the Executive Branch discretion to determine the applicability of the statute to products falling within that definition—holding that the statutory definition, standing alone, provided the requisite intelligible principle. *See* 654 F.2d at 1036 n.2 ("The Secretary [of the Treasury] shall publish and revise at least annually in the Federal Register a list of these and any additional explosives which he determines to be within the coverage of this chapter.") (quoting 18 U.S.C. § 841 (1976)). This case may be resolved by a single citation to *Womack*.

Plaintiffs make only one argument in response: according to Plaintiffs, "[t]he federal statute in *Womack* applied the offense to all 'explosives,' and there was no suggestion that the [Secretary of the Treasury] was authorized to (i) find that something fit the definition of 'explosive,' but then (ii) decline to list it in his discretion." Pls.' Reply Mem. in Supp. of Mot. for Prelim. Inj. ("Pls.' PI Reply") at 5, ECF No. 29. Therefore, argue Plaintiffs, "*Womack* thus addressed a question materially distinct from the TCA." *Id.* But even accepting uncritically Plaintiffs' unsupported *ipse dixit* that this factual distinction even exists,[1] it still provides no basis for ducking the Fifth Circuit's binding precedent in

[1] In fact, the statute in *Womack* only required the Secretary of the Treasury to "publish and revise *at least annually* . . . a list of these and any additional explosives which he determines to be within the coverage of this chapter." 654 F.2d at 1036 n.2 (citing 18 U.S.C. § 841 (1976)) (emphasis added). In other words, the statute contemplated a scenario in which the agency identified an additional product that met the definition of "explosives," but then declined to list it for another 11 months. And even with respect to the annual publishing requirement, it was only triggered when the Secretary

Womack. Indeed, Plaintiffs do not explain *why* this supposed distinction should matter. And there is no reason to believe that it should. In both statutes, Congress undisputedly delegated authority to the Executive Branch to either "deem[]," 21 U.S.C. § 387a(b), or "determine[]," 18 U.S.C. § 841 (1976), whether certain congressionally imposed obligations shall apply to particular products. In both statutes, Congress declined to provide any explicit triggering criteria, or to require any particular predicate factual finding. And in both statutes, Congress provided (1) a list of exemplary products that were to be immediately subject to the statute's coverage, and (2) a precise definition that the agency was to apply, in its discretion, in considering whether any additional, unlisted products should also be covered in the future (as long as they fell within the definition Congress provided). *Womack* presents no distinction at all, let alone a material one. The Fifth Circuit has thus already held that this statutory structure is constitutional, and that is enough to resolve this case.[2]

Plaintiffs also seek to rely on *Touby v. United States*, 500 U.S. 160 (1991), but that decision, if anything, supports the Government. In *Touby*, the Supreme Court *rejected* the argument that the Controlled Substances Act, 21 U.S.C. § 801 *et seq.*, had unconstitutionally delegated authority to the Attorney General to temporarily designate drugs as "controlled substances," subject to the statute's five "schedules" of regulation—even though Congress had authorized the Attorney General to do so

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"determined" that a new explosive should be covered; he could always decline to make such a formal determination with respect to a particular explosive, thus keeping it outside the statute's coverage indefinitely. The scope of the delegated authority at issue in *Womack*, in reality, is thus on all fours with the authority delegated to the FDA in 21 U.S.C. § 387a(b).

[2] *Womack* also refutes Plaintiffs' claim that Defendants "have not cited any case rejecting a nondelegation challenge to a statute that is devoid of a standard." Pls.' PI Reply at 13. To be clear, Defendants of course do not consider that to be an accurate description of the Tobacco Control Act—particularly in light of the substantial guidance provided by Congress in the overall statutory scheme, *see infra* Section I(C)—but if what Plaintiffs are referring to is the absence of any explicit, congressionally imposed textual requirement that the agency make some particular factual finding in reference to some precise set of statutory criteria, this case is no different from *Womack* on that issue. (Another example, *Loving v. United States*, 517 U.S. 748, 772 (1996), is discussed below, *see infra* at 9.)

without observance of all the procedures required before a drug is "permanently" scheduled. 500 U.S. at 160. In fact, the *Touby* challengers "wisely concede[d]" the existence of an intelligible principle under existing precedent, *id.* at 165, and instead tried to persuade the Supreme Court to adopt a *higher* standard—at least "when Congress authorizes another Branch to promulgate regulations that contemplate criminal sanctions," *id.* at 165-66. The Court did not bite. It surely is no help to *Plaintiffs* that the Supreme Court in *Touby* rejected a nondelegation challenge to a statutory structure that is similar to the Tobacco Control Act—just as the Fifth Circuit did in *Womack*.

To be sure, the statute in *Touby*, "[a]lthough . . . featur[ing] fewer procedural requirements than the permanent scheduling statute," 500 U.S. at 166, listed several factors for the Attorney General to consider in deciding whether to temporarily "schedule" a controlled substance. Those factors were quite broad (*e.g.*, "risk . . . to the public health," *id.*), but the Supreme Court never had any occasion (at least in *Touby*) to decide how much (if any) of that specificity was constitutionally *required*, particularly given plaintiffs' concession that the statute provided an intelligible principle. In any event, *Womack* remains directly on point, and Plaintiffs' argument that the statute in *Touby* provided more guidance than the Tobacco Control Act is ultimately addressed to the separate *American Power & Light* prong requiring that Congress adequately identify the "general policy" for the agency to pursue. 329 U.S. at 105. For the reasons explained below, *see infra* Section I(C), Congress did so here.

C. Congress identified the general policy it intended the agency to pursue.

1. As explained in Defendants' combined memorandum (pp. 30-36), the Tobacco Control Act as a whole defines "the general policy," *American Power & Light*, 329 U.S. at 105, for the agency to pursue. In brief, Congress did so by (1) explicitly listing its purposes;[3] (2) separately authorizing the

[3] *See, e.g.*, Pub. L. No. 111-31 § 3(2), 123 Stat. 1776, 1781 (2009) (*codified at* 21 U.S.C. § 387 (notes)) ("to ensure that the Food and Drug Administration has the authority to address issues of

FDA to "require restrictions on the sale and distribution" of any "tobacco product, if the Secretary determines that such regulation would be appropriate for the protection of the public health," 21 U.S.C. § 387f(d)(1); (3) defining the FDA's mission as "promot[ing] the public health by promptly and efficiently reviewing clinical research and taking appropriate action on the marketing of regulated products," *id.* § 393(b)(1); and (4) granting the FDA general "authority to promulgate regulations for the efficient enforcement of [the Federal Food, Drug, and Cosmetic Act]," *id.* § 371(a).

According to Plaintiffs, "[t]he *FDA* writes that '[t]he standards of the [challenged] statute are not to be tested in isolation but must derive meaningful content from the purpose of the statute and its factual background and the statutory context in which the standards appear.'" Pls.' PI Reply at 7-8 (quoting Defs.' Combined Mem. at 30) (emphasis added). That is an odd way to put it—that sentence was a direct quote from the Fifth Circuit, *see Womack*, 654 F.2d at 1037, which in turn was discussing *American Power & Light*, in which the Supreme Court used nearly identical language, *see* 329 U.S. at 104 ("[T]hese standards need not be tested in isolation. They derive much meaningful content from the purpose of the Act, its factual background and the statutory context in which they appear."). It was not "[t]he FDA," Pls.' PI Reply at 7, that created this doctrinal methodology, which requires analysis of the statutory scheme as a whole (including consideration of statutory context and purpose)—it was the Supreme Court of the United States.

Plaintiffs argue that the plurality opinion in *Gundy* "supports Plaintiffs, not Defendants." Pls.' PI Reply at 10. But regarding the significance to be attributed to congressional statements of purpose, the *Gundy* plurality *rejected* an argument quite similar to the argument that Plaintiffs make here. *Compare*

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particular concern to public health officials, especially the use of tobacco by young people and dependence on tobacco"); *id.* § 3(4) ("to provide new and flexible enforcement authority to ensure that there is effective oversight of the tobacco industry's efforts to develop, introduce, and promote less harmful tobacco products").

139 S. Ct. at 2127 ("Gundy urges us to ignore SORNA's statement of purpose because it is 'located in the Act's preface' rather than 'tied' specifically to § 20913(d). . . . But the placement of such a statement within a statute makes no difference."), *with* Pls.' PI Reply at 8 ("[E]ven if one could discern a guiding principle from the statements of purpose, reading the statute as a whole requires recognizing that Congress limited the TCA's application to a subset of tobacco products, precluding any attempt to derive 'meaningful content' from the prefatory section of the Act alone.").

In any event, even setting aside the *Gundy* plurality, prior Supreme Court and Fifth Circuit majorities have repeatedly taken the same approach. *See, e.g.*, *Mistretta v. United States*, 488 U.S. 361, 374-75 (1989) (beginning its nondelegation analysis by consideration of the "three goals" and the "four purposes" that Congress had provided to the Sentencing Commission); *Lichter v. United States*, 334 U.S. 742, 785 (1948) ("The purpose of the Renegotiation Act and its factual background establish a sufficient meaning for 'excessive profits' as those words are used in practice."); *American Power & Light*, 329 U.S. at 104-05; *Yakus v. United States*, 321 U.S. 414, 425-27, 449 (1944) (considering the Emergency Price Control Act of 1942's seven "stated purposes to ascertain what, if any, limits the statute places upon the Administrator's exercise of his powers," in upholding a delegation to the Price Administrator to fix commodity prices that would be "fair and equitable" and that would "effectuate the purposes" of the statute); *N.Y. Cent. Sec. Corp. v. United States*, 287 U.S. 12, 24 (1932) ("Appellant insists that the delegation of authority to the Commission is invalid because the stated criterion is uncertain. That criterion is the 'public interest.' It is a mistaken assumption that this is a mere general reference to public welfare without any standard to guide determinations. The purpose of the Act, the requirements it imposes, and the context of the provision in question show the contrary."); *Whaley*, 577 F.3d at 264 ("SORNA's statement of purpose, to 'establish[] a comprehensive national system' of sex offender registration to 'protect the public from sex offenders and offenders against children,' 42

U.S.C. § 16901, is an intelligible principle that guides the Attorney General in exercising his discretion."); *United States v. Gordon*, 580 F.2d 827, 839-40 (5th Cir. 1978).[4]

Plaintiffs further argue that the "FDA cannot claim that its heavy-handed, indiscriminate regulation of ENDS is clearly supported by the TCA's purpose statements when such regulation threatens serious damage to Congress's aim of 'promot[ing] cessation to reduce disease risk and the social costs associated with tobacco-related diseases[.]'" Pls.' PI Reply at 9 n.1 (quoting Pub. L. No. 111-31 § 3(9), 123 Stat. at 1782). Unsurprisingly, Defendants do not agree with Plaintiffs' description of the FDA's efforts to regulate the vaping industry. And the evidence is mixed with respect to whether e-cigarettes help smokers quit in meaningful numbers. *See* Defs.' Combined Mem. at 11-12 (citing conflicting studies). But even if Plaintiffs were right, that sort of argument—*i.e.*, that the FDA has somehow acted *contrary to* Congress's stated goals—is no help to their nondelegation claim. Indeed, Plaintiffs' argument on this issue is itself an illustration of what should be obvious to any reader of the Tobacco Control Act: Congress provided ample guidance to the agency, and more than enough to define "the general policy," *American Power & Light*, 329 U.S. at 105, that the agency is to pursue. Plaintiffs apparently believe that the FDA has failed to execute those congressional purposes. But even if Plaintiffs were right about that, the very existence of those identifiable congressional goals undermines, rather than supports, Plaintiffs' nondelegation claim.[5]

2. Plaintiffs also protest that "[t]he constitutional requirement of an intelligible principle is not ignored in a complex or 'fast-moving industry.'" Pls.' PI Reply at 11. That is of course correct,

[4] This is among the reasons why Plaintiffs' fact-bound attempt (*see* Pls.' PI Reply at 8-9) to distinguish the particular statute at issue in *American Power & Light* is unavailing: the legal principles from that case on which Defendants rely appear in several other cases that Plaintiffs do not address.

[5] Plaintiffs similarly assert that the Tobacco Control Act "reflects a legislative determination to leave many types of tobacco products entirely unregulated." Pls.' PI Reply at 10. But while Congress *initially* applied the statute's requirements only to certain products, it also expressly provided that "any other tobacco products" may become subject to the statute's coverage. 21 U.S.C. § 387a(b).

and Defendants have not argued to the contrary. The Fifth Circuit has been clear, however, that "the complexity of the area at which the legislation is directed and the susceptibility to change of the area in question," *Gordon*, 580 F.2d at 839, are relevant to the nondelegation analysis, and Plaintiffs do not dispute that consideration of those issues weighs in favor of Defendants. In fact, Congress's delegation of flexible authority to the FDA to exercise discretion with respect to the definition of "tobacco product" has been powerfully vindicated by the subsequent and sudden explosion of this massive and novel e-cigarette industry—now the fastest growing segment of the tobacco market—which was only its infancy when the TCA was first enacted ten years ago.

3. As Defendants explained in their combined memorandum (pp. 34-35), the general policy that Congress adopted—that is, promoting the public health through efficient enforcement of the statutory requirements that Congress imposed upon the tobacco industry—is more than sufficient given the limited scope of the authority delegated in 21 U.S.C. § 387a(b). When it delegates sweeping authority—such as power to "set[] air standards that affect the entire national economy"—Congress "must provide substantial guidance" to the agency. *Whitman v. American Trucking Ass'ns*, 531 U.S. 457, 475 (2001). By contrast, when Congress confers narrow authority—such as the discretion to define or implement one statutory term—it "need not provide any direction." *Id.* In such cases, "the question to be asked is not whether there was any explicit principle telling the" Executive how to exercise its statutory discretion, "but whether any such guidance was needed, given the nature of the delegation and the officer who is to exercise the delegated authority." *Loving*, 517 U.S. at 772. Plaintiffs offer no response to Defendants' discussion of *Loving*.

D. Plaintiffs' remaining arguments lack merit.

1. Plaintiffs' preliminary-injunction reply doubles down on their revisionist interpretation of *Panama Refining Co. v. Ryan*, 293 U.S. 388 (1935), which is one of two Supreme Court opinions from

1935 holding unconstitutional under the nondelegation doctrine a provision of the Recovery Act, a comprehensive law "to regulate the entire economy" enacted during the depths of the Great Depression, *American Trucking*, 531 U.S. at 474.[6] Plaintiffs' laser-like focus on *Panama Refining* is perhaps unsurprising, given that it is plainly an outlier in the robust history of the Supreme Court's nondelegation jurisprudence. *See* Defs.' Combined Mem. at 20-25 (describing this history in detail).

In any event, even considering the argument on its own terms, Plaintiffs' interpretation of *Panama Refining* is—like many of their other arguments—foreclosed by precedent. As Plaintiffs read the case, "Congress had defined a *narrow* subject matter," Pls.' PI Reply at 3 (emphasis added), such that the statute "did *not* confer limitless authority on the President to regulate any industry in any way he saw fit," but rather "was constrained to only a subset of petroleum products." Pls.' Mem. in Supp. of Mot. for Prelim. Inj., ECF No. 17, at 38-39 (emphasis added). But Plaintiffs' view of that statutory scheme is not shared by the Supreme Court, which has described the statute at issue in *Panama Refining* as having "provided literally no guidance for the exercise of discretion." *American Trucking*, 531 U.S. at 474; *accord Mistretta*, 488 U.S. at 373 n.7 ("In *Schechter* and *Panama Refining* the Court concluded that Congress had failed to articulate *any* policy or standard that would serve to confine the discretion of the authorities to whom Congress had delegated power.") (emphasis added). Plaintiffs offer no response to Defendants' argument that the Supreme Court's characterization of *Panama Refining* bears no resemblance to Plaintiffs'. But the Supreme Court's interpretations of its own decisions are no less binding on this Court than any other applicable Supreme Court precedent. *Cf. Hulsey v. Am. Brands, Inc.*, No. C-97-003, 1997 WL 271755, at *3 (S.D. Tex. Apr. 7, 1997) ("The proposition that a decision of the Fifth Circuit Court of Appeals incorrectly interprets an opinion by the Supreme Court of the

[6] Plaintiffs now appear to concede that the other 1935 decision, *A.L.A. Schechter Poultry Corp. v. United States*, 295 U.S. 495 (1935), is no help to them here, given their failure to respond to Defendants' arguments (Defs.' Combined Mem. at 38-39) about its inapplicability.

United States must be addressed to the Fifth Circuit, the decisions of which are binding on this Court."), *aff'd*, 139 F.3d 898 (5th Cir. 1998), *cert. denied*, 525 U.S. 868 (1998).

The closest Plaintiffs come to an interpretation of *Panama Refining* that is consistent with the Supreme Court's is their belated acknowledgment that the Recovery Act "'establish[ed] *no criterion* to govern the President's course'"; "[i]nstead, it gave him 'an *unlimited* authority to determine the policy and to lay down the prohibition, or not to lay it down, as he may see fit.'" Pls.' PI Reply at 4 (quoting *Panama Refining*, 293 U.S. at 415) (emphases added). The Tobacco Control Act, however, could not be described in similar terms. As Defendants have explained, this delegation is confined to a binary choice about whether to apply a pre-existing set of well-defined, congressionally drafted obligations to a subset of products meeting the statutory definition of "tobacco product." And Congress provided ample guidance to the agency in exercising that narrow discretion, particularly when the statutory scheme *as a whole* is considered in the context of Congress's (explicitly listed) policy goals.

2. Plaintiffs continue to protest that FDA's exercise of the authority delegated by 21 U.S.C. § 387a(b) necessarily involves subjective policy judgment. *See, e.g.*, Pls.' PI Reply at 11 ("§ 387a(b) codifies Congress' deliberate choice to strictly limit the application of the TCA, but simultaneously punt to the Executive the question whether it shall be extended to other products, without establishing a policy.") (emphasis omitted); *id.* at 17 ("legislative policy is being hammered out in the Executive branch rather than Congress"). But the (routine) fact that a delegation carries with it the responsibility to exercise policy judgment raises no concerns under binding precedent. "Congress is not confined to that method of executing its policy which involves the least possible delegation of discretion to administrative officers." *Yakus*, 321 U.S. at 425-26. Indeed, "[i]t is no objection that the determination of facts and the inferences to be drawn from them in the light of the statutory standards and declaration of policy call for the exercise of judgment, and for the formulation of subsidiary

administrative policy within the prescribed statutory framework." *Id.* at 425. To put it more sharply: the Supreme Court's decisions "do not at all suggest that delegations of this type may not carry with them the need to exercise judgment on matters of policy." *Mistretta*, 488 U.S. at 378.

3. Plaintiffs misunderstand Defendants' statement that "'at least *some* FDA oversight of *some* of these potentially harmful products is in the public interest—at least with respect to the most dangerous and youth-friendly products and marketing practices.'" Pls.' PI Reply at 12 (quoting Defs.' Combined Mem. at 45). That was not a legal "fallback" argument, suggesting that "subjecting ENDS to the TCA would pass muster under an appropriately limited (hypothetical) version of the TCA." Pls.' PI Reply at 12. In fact, that argument was part of Defendants' opposition to Plaintiffs' motion for a preliminary injunction, for which consideration of the public interest is relevant. *See* Defs.' Combined Mem. at 42 (Section II(A)). As explained, granting Plaintiffs' requested preliminary injunction would harm the public health—an independent basis for denial of *Plaintiffs'* motion, regardless of the legal merit of these claims. But that has nothing to do with the constitutional argument that forms the basis for *Defendants'* motion that is the subject of this memorandum.

II. THERE IS NO BASIS FOR DISCOVERY.

Plaintiffs assert that "the deeming provision is unconstitutional on its face," Pls.' Mem. in Opp'n to Defs.' Mot. to Dismiss ("Pls.' MTD Opp'n") at 5, ECF No. 32—yet simultaneously insist that they are entitled to discovery before the Court resolves that pure question of law. They are not.

a. There is no basis for *any* discovery in this case, for the reasons explained below. Regardless, it cannot reasonably be disputed that no discovery is needed to resolve Defendants' motion to dismiss, which challenges the sufficiency of the complaint—even accepting all of Plaintiffs' plausible, well-pleaded factual allegations as true. If Plaintiffs have failed to state a claim even with the

presumption of truth afforded to their factual allegations[7]—allegations which, in any event, are largely irrelevant to the pure question of law raised by Plaintiffs' nondelegation claim—then that legal defect warrants immediate dismissal of the complaint, in its entirety, as a matter of basic federal procedure. That is why even in cases (unlike this one) in which discovery could ultimately be necessary to resolve the merits, courts routinely stay or defer discovery until after resolution of a dispositive motion. *See, e.g.*, *Corwin v. Marney, Orton Invs.*, 843 F.2d 194, 200 (5th Cir. 1988) ("[A] trial court may properly exercise its discretion to stay discovery pending a decision on a dispositive motion."). Here, there are no pending discovery requests to stay—only suggestions that Plaintiffs believe discovery will ultimately be necessary. But if the Court grants Defendants' motion to dismiss, this case is over. So the Court should first decide that motion, without regard to Plaintiffs' plans for future discovery in the event Defendants' motion were denied. Plaintiffs' claimed "right to discovery," Pls.' MTD Opp'n at 6, simply does not exist in a case like this, in which the complaint cannot survive a Rule 12 motion. *See Iqbal*, 556 U.S. at 678-79 ("Rule 8 marks a notable and generous departure from the hypertechnical, code-pleading regime of a prior era, but it does not unlock the doors of discovery for a plaintiff armed with nothing more than conclusions."); *McClanahan v. Davis*, 49 U.S. 170, 183 (1850) ("The complainant having, in our judgment, failed to set forth any foundation for relief, the right to the discovery, which is claimed as incidental, of course fails with it.").

[7] Plaintiffs imply that their legal arguments or conclusions are entitled to deference. *See* Pls.' MTD Opp'n at 3. They are not. *See, e.g.*, *Ashcroft v. Iqbal*, 556 U.S. 662, 678-79 (2009) ("Although for the purposes of a motion to dismiss we must take all of the factual allegations in the complaint as true, we 'are not bound to accept as true a legal conclusion couched as a factual allegation.'" (quoting *Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 555 (2007))). The bare quotation included without commentary in *Inclusive Communities Project, Inc. v. Lincoln Prop. Co.*, 920 F.3d 890 (5th Cir. 2019), relied upon by Plaintiffs, is not to the contrary. There, the Fifth Circuit did as the Supreme Court requires: it neutrally applied the law—and in fact resolved the central legal ambiguity in that case *against* the plaintiff at the motion-to-dismiss stage, *see id.* at 903—in affirming dismissal of the complaint, *id.* at 912.

b. Even setting aside Defendants' motion to dismiss, *none* of Plaintiffs' proposed discovery is appropriate—either now or later—given the purely legal nature of Plaintiffs' only claim. First, Plaintiffs argue that "discovery is necessary to refute the background picture the Defendants attempt to paint with their voluminous (but superficial) references to factual material outside Plaintiffs' Complaint." Pls.' MTD Opp'n at 4. Even ignoring Plaintiffs' failure to cite any authority for the proposition that discovery regarding the "background picture" of a case even satisfies the basic standard for discoverable information in Federal Rule of Civil Procedure 26(b)(1), it was entirely appropriate to include a high-level summary of the factual background of this novel industry, for the Court's benefit, in Defendants' combined memorandum. That combined memorandum was not just filed in support of Defendants' motion to dismiss, but also in opposition to Plaintiffs' motion for a preliminary injunction, for which the Court is not limited to consideration of materials referenced in or relied upon in the complaint.[8] *See, e.g.*, *Sierra Club, Lone Star Chapter v. FDIC*, 992 F.2d 545, 551 (5th Cir. 1993) ("[A]t the preliminary injunction stage, the procedures in the district court are less formal, and the district court may rely on otherwise inadmissible evidence, including hearsay evidence."); *ADT, LLC v. Capital Connect, Inc.*, 145 F. Supp. 3d 671, 682 (N.D. Tex. 2015) (considering "evidence in the form of declarations and exhibits" as part of preliminary-injunction briefing). In any event, much of that background material would also be appropriate to consider as part of a pure motion to dismiss: as either "documents incorporated into the complaint by reference" or "matters of which a court may take judicial notice." *Tellabs, Inc. v. Makor Issues & Rights, Ltd.*, 551 U.S. 308, 322 (2007).

[8] According to Plaintiffs, Defendants' decision to file one combined memorandum means that Defendants "have forefeited [sic] their opportunity to seek final dismissal on the merits without any discovery." Pls.' MTD Opp'n at 5. Plaintiffs, again, cite no authority for that baseless proposition. Defendants filed one combined memorandum (rather than two repetitive and overlapping memoranda) out of respect for the Court's time, because Defendants' primary argument in opposition to entry of a preliminary injunction is identical to Defendants' argument for dismissal under Federal Rule of Civil Procedure 12(b)(6): that is, that Plaintiffs' nondelegation claim is meritless.

This Court need not decide any of that, however. As Defendants made clear in the background section of their combined memorandum, "[n]one of Defendants' arguments for dismissal in this case require the Court to opine on the factual accuracy of that material." Defs.' Combined Mem. at 9-10 n.8. That is because of the purely legal nature of Plaintiffs' only claim: a facial constitutional challenge to one provision in the Tobacco Control Act. Either 21 U.S.C. § 387a(b) is constitutional or it is not, but that question has nothing to do with, for example, whether or not "combustible tobacco products are far more dangerous than vapor products." Pls.' MTD Opp'n at 5. Plaintiffs seemingly recognize this, reiterating that theirs is a facial challenge. *See id.* ("Plaintiffs note that they do not concede that any of Defendants' arguments or evidence actually undermine the constitutional challenge—the fact is that the deeming provision is unconstitutional on its face."). But whether they recognize it or not, discovery on a claim that raises a pure question of law is inappropriate. *See, e.g.*, *Brazos Valley Coal. for Life, Inc. v. City of Bryan*, 421 F.3d 314, 327 (5th Cir. 2005) ("[T]he City's motion for summary judgment raised pure questions of law. Appellants do not even attempt to show, nor can we readily imagine, how any additional discovery would have been necessary to answer these purely legal questions.").

To be sure, under the nondelegation doctrine, "the degree of agency discretion that is acceptable varies according to the scope of the power" delegated. *American Trucking*, 531 U.S. at 475. But "the scope of the power" delegated by a federal statute is a legal question—not one that turns on the "economic impact," Pls.' MTD Opp'n at 5, of any particular agency action *subsequently* taken *pursuant to* that authority. So Plaintiffs' desire for discovery regarding "the size of the ENDS industry and other newly-deemed industries (cigars, etc.), the jobs at stake, etc.," *id.*, is impossible to square with the nature of their claim: a facial challenge to 21 U.S.C. § 387a(b), which was signed into law in 2009, before the vaping industry even *existed* in any form that remotely resembles it today. No facts

about the past, present, or future economic impact of any particular action by the FDA are relevant to the question of whether Congress violated the constitution.

Plaintiffs also assert with confidence that the "the uptick in youth vaping is attributable almost entirely to a distinctive subset of vaping products (namely, Juul and other pod-based, closed systems), and not the open-system devices that the USVA's members sell." Pls.' MTD Opp'n at 7. But nothing turns on that factual question here. The question at stake in this lawsuit is whether 21 U.S.C. § 387a(b)—a statutory provision enacted in 2009—is constitutional. The technological subtleties distinguishing "closed-system" and "open-system" vaping systems, and their comparative contributions to the youth-vaping epidemic in 2019, have nothing to do with the constitutional separation of powers, and discovery on that subject is therefore unnecessary.[9]

Finally, Plaintiffs suggest (Pls.' MTD Opp'n at 7-8) that they intend to seek discovery in support of what can only be described as a conspiracy theory: accusing the scientists, doctors, and policymakers at the FDA and the Centers for Disease Control and Prevention ("CDC") of intentionally misleading the American people about EVALI (E-Cigarette or Vaping Product Use Associated Lung Injury), a recently identified disease that was briefly referenced (primarily in footnotes) in Defendants' combined memorandum. *See* Defs.' Combined Mem. at 2 & nn.2-3. That

[9] As explained above, Plaintiffs' proposed discovery has little to do with their facial challenge to the Tobacco Control Act, or even the deeming rule, but instead appears to arise from a desire to scrutinize more recent exercises (and even *proposed* exercises) of FDA's regulatory and enforcement authority. *See, e.g.*, Pls.' MTD Opp'n at 7 (discussing recent data from the National Youth Tobacco Survey); Pls.' PI Reply at 14 (discussing what Plaintiffs describe as the "imminent flavor ban"). Even if any of those agency actions (or potential future agency actions) were at issue in this lawsuit, *but see* Defs.' Combined Mem. at 49-50, judicial review of allegedly unlawful agency action would be confined (at most) to an administrative record prepared by the agency. *See, e.g.*, *Camp v. Pitts*, 411 U.S. 138, 143 (1973). And the inclusion of constitutional claims would not justify departure from Administrative Procedure Act record-review principles. *See* 5 U.S.C. § 706(2)(B); *Bellion Spirits, LLC v. United States*, 335 F. Supp. 3d 32, 43 (D.D.C. 2018).

innuendo is baseless. To the extent this disease has been "sensationalized," Pls.' MTD Opp'n at 7, in the press, that is not the result of any action taken by FDA or CDC, but rather the nature of the disease: with the lungs of affected patients described by doctors at the Mayo Clinic as "like the kind of change you would expect to see in an unfortunate worker in an industrial accident where a big barrel of toxic chemicals spills, and that person is exposed to toxic fumes and there is a chemical burn in the airways"; or "like those seen in people exposed to poisons like mustard gas, a chemical weapon used in World War I."[10] The sudden, nationwide onset of 2,290 cases and 47 deaths (so far) cannot be ignored by the FDA. *See* Ex. 1, CDC, *Outbreak of Lung Injury Associated with the Use of E-Cigarette, or Vaping, Products.*[11]

Plaintiffs assert that it "should have been obvious" to the FDA and the CDC, that those injuries and deaths "arose from black-market THC-based products, not nicotine e-liquids." Pls.' MTD Opp'n at 7-8.[12] To be sure, as its (still-ongoing) investigation has progressed, recently, "CDC has identified vitamin E acetate"—a substance that "is used as an additive, most notably as a thickening agent in THC-containing e-cigarette, or vaping, products"—as a particular "chemical of concern." Ex. 1. But government investigators will not jump to premature conclusions that are not supported by hard science: "While it appears that vitamin E acetate is associated with EVALI, evidence is not yet sufficient to rule out contribution of other chemicals of concern to EVALI. Many different

[10] Denise Grady, *Lung Damage from Vaping Resembles Chemical Burns, Report Says*, N.Y. TIMES, Oct. 2, 2019, *available at* https://www.nytimes.com/2019/10/02/health/vaping-illnesses.html (citing Yasmeen M. Butt, M.D., *et al.*, *Pathology of Vaping-Associated Lung Injury*, NEW ENG. J. OF MED. (first published Oct. 2, 2019), *available at* https://www.nejm.org/doi/pdf/10.1056/NEJMc1913069?articleTools=true).

[11] This web page is updated weekly, but Defendants have attached as Exhibit 1 a copy of the version last updated on November 21, 2019. This page is also available at https://www.cdc.gov/tobacco/basic_information/e-cigarettes/severe-lung-disease.html.

[12] "THC" stands for tetrahydrocannabinol, which is the principal psychoactive ingredient in most cannabis or marijuana products.

substances and product sources are still under investigation, and it may be that there is more than one cause of this outbreak." *Id.*

That cautious attitude is appropriate, given that in a recent sample of 29 patients, although all tested positive for vitamin E acetate, no other single substance was detected in each patient: "THC was identified in 82% of the samples and nicotine was identified in 62% of the samples." *Id.* Although Plaintiffs may believe it was and is "obvious" that the only potential culprits are "black-market THC-based products," Pls.' MTD Opp'n at 7-8, that confidence is hard to square with the fact that 18% of EVALI samples tested apparently had *no* detectable THC—data that are consistent with reports from patients, many of whom have reported "exclusive use of nicotine-containing products."[13] Ex. 1.

In any event, the as-yet-uncertain scientific provenance of this alarming spate of illness and death associated with vaping is not a subject that this Court needs to address: although that uncertainty underscores the importance of the FDA's efforts to keep watch over this industry, it ultimately has nothing to do with the question of whether 21 U.S.C. § 387a(b) is constitutional. So discovery on that subject will never be "relevant to any party's claim or defense" or "proportional to the needs of the case," Fed. R. Civ. P. 26(b)(1)—even if there were any merit to Plaintiffs' baseless allegations about how the FDA and CDC have handled the latest vaping-related public-health crisis.[14]

CONCLUSION

Plaintiffs' complaint should be dismissed, with prejudice, in its entirety.

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[13] Plaintiffs' use of the phrase "black-market" to distinguish their own businesses is also imprecise (at best) given that *any* e-cigarette products currently on the market (including those containing only nicotine) without premarket authorization—that is, *all* of the e-cigarette products currently sold at Big Time Vapes and by the members of the U.S. Vaping Association—are being sold in undisputed violation of the Tobacco Control Act. *See* 21 U.S.C. § 387j(a)(1)-(2).

[14] Although Defendants are confident that discovery will never be necessary here, Defendants reserve the right to oppose, at the appropriate time, any future discovery for any reason, or to assert any applicable privilege or protection, including based on arguments that do not appear in this brief.

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Respectfully submitted,

Of counsel:

ROBERT P. CHARROW
General Counsel
U.S. Dep't of Health and Human Services

STACY CLINE AMIN
Chief Counsel
Food and Drug Administration
Deputy General Counsel
Department of Health and Human Services

PERHAM GORJI
Deputy Chief Counsel for Litigation

WENDY S. VICENTE
Senior Counsel

NOAH T. KATZEN
Associate Chief Counsel
Office of the Chief Counsel
Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993-0002

JOSEPH H. HUNT
Assistant Attorney General

D. MICHAEL HURST, JR.
United States Attorney

ERIC B. BECKENHAUER
Assistant Director

/s/ Stephen M. Pezzi
STEPHEN M. PEZZI
Trial Attorney
United States Department of Justice
Civil Division, Federal Programs Branch
1100 L Street, NW
Washington, DC 20005
Tel: (202) 305-8576
Email: stephen.pezzi@usdoj.gov

EMILY S. NOBILE
Assistant United States Attorney
Office of the United States Attorney
Southern District of Mississippi

Counsel for Defendants